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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,649

10/11/2005

Giovanni Pozzi

2965-195

1389

6449

7590

04/04/2007

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
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3 MONTHS

04/04/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/04/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,649	<b>Applicant(s)</b> POZZI ET AL.	
	<b>Examiner</b> Mark L. Berch	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over 6093814.

See example 4, which provides for a process making the R2=trityl, R1=H material. Note that the initial acylation, using the tritylated acylating agent, is done using 44.0 mmol of the cephalosporin, and 88.0 mmol of the tributyl amine. Half of the amine will be consumed in the acylation process, meaning that some or all the remaining amine will be there to produce the salt, i.e. the tributyl ammonium salt or tritylated cefdinir. Thus, the material that exists just prior to adding the toluene sulfonic acid is in fact a solution of the tributyl ammonium salt of tritylated cefdinir.

With regard to claim 12, examples 6-8 show the conversion to cefdinir. The process of the reference has the additional step of going through the solvate of Formula II, but claim 12 has "comprises", so it is open-ended with regard to additional steps.

Responding to the previous anticipation, applicants have excluded the tributylamine. However, the reference teaches that several amines can be used, and names two as preferred: triethylamine and tributylamine; see column 5, line 63. Thus, the use of

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triethyl amine, or any of the other amines in that sentence would have been obvious. Note that triethylamine was in fact used in example 3, a clear guidepost to the use of that amine.

Claim 13 is not rejected over the reference, as the reference contains no suggestion to protect the amino group.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-10, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "acyl" is indefinite. Does this embrace acids of S? P? As? What does the stem look like, i.e. if the acyl is e.g. RC(O), what is R? The traverse is unpersuasive. Applicants have provided several references, and their diversity is evidence that the term has not one generally accepted meaning. The McGraw Hill reference, cited in the remarks, says that this is RCO, where R is aliphatic, alicyclic or aromatic. That would exclude HCO, since H is none of these. However, applicants have said in their remarks that HCO is indeed intended, and in fact, claim 2 names it. Thus, applicants are submitting a reference which contradicts their own assertion. This definition would also exclude ClC(O) or HOC(O). The Condensed Chemical Dictionary reference is broader, covering any organic

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radical, and thus would include something like  $\text{ClC(O)}$ , as chloroformic acid is considered an organic acid. The Wikipedia reference is even broader, because it is not limited to  $\text{RCO}$  at all. The reference names “sulfonic acids, phosphonic acid and some others”. Thus, applicants have provided references which themselves show that there is no one generally accepted meaning, but an assortment of meanings. What about  $\text{CH}_3\text{C(S)}^-$ ?  $\text{CH}_3\text{C(O)O}^-$ ?

The traverse is unpersuasive. Applicants discuss the matter for page after page, and yet nowhere do they state how one of ordinary skill in the art could have arrived at that definition rather than a different one.

Instead, applicants resort on page 11 to misrepresenting the references cited, concluding that there is “no substantial difference”. With regard to the Wikipedia reference, applicants present the reference as saying that it is of the form “ $\text{RC(=O)}^-$ ”, even though the reference explicitly states, “Acyl groups can also be derived from other types of acids such as sulfonic acids, phosphonic acids, and some others.” Instead applicants point to this: “Most commonly, the acyl group is derived from a carboxylic acid.” Yes, of course, this is true; the most common acids are carboxylic acids; there are far more of them than e.g. sulphonic acids. But the reference’s language is explicit: The term acyl not only includes groups derived from the common carboxylic acids, but from other acids as well.

In response to applicants brushing off these other types, the examiner cites the reference “acyl groups (IUPAC Compendium of Chemical Terminology 2nd Edition (1997))”. The reference gives 6 examples of acyl groups; only one of these 6 falls into the category of  $\text{RC(O)}^-$ .

With regard to The McGraw Hill reference and the Condensed Chemical Dictionary there are sharp differences between the two, which applicants seek to minimize by ignoring

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the plain language of the text. The text says "RCO, where R may be aliphatic, alicyclic or aromatic". That is understood as saying that R is permitted to be those three choices.

Applicants analysis would completely ignore this, and permit R to be anything at all, which is not what the reference conveys. Thus, since R is not an aliphatic, alicyclic or aromatic group, HC(O) would not be included, and indeed, formyl is often not included in the notion of what an acyl group is.

In response to this argument that R denotes anything at all, the examiner cites the reference "acyl" (Academic Press Dictionary of Science and Technology). This states: "The general formula is RCO-, where R is aromatic, aliphatic, or alicyclic". Note that this has the verb "is". The examiner also cites "acyl group" (Datasegment.com), which states: "any group or radical of the form RCO- where R is an organic group". That definition, like McGraw Hill, would exclude ordinary choices like R=H, Hal, OH, as these are not organic moieties. Yet another definition appears in "THE FRIEDEL-CRAFTS ACYLATION OF BENZENE", which states, "An acyl group is an alkyl group attached to a carbon-oxygen double bond." In fact, definitions of acyl in which R is not everything, and does not go beyond organic groups (e.g. excludes H, halogen, amino, OH, etc) are fairly common in the patent literature. See 6346583, 20030225007, 5114958, 6153645, 6319955, 20050203006, 20040019198.

This is not, then, an issue of the lack of "mathematical precision". Some perfectly ordinary groups such as formyl or benzenesulphonyl or phsophoryl would be considered acyl by some and not by others. Because the specification gives no guidance as to which of the many conventional uses of the term was intended, the term must be considered ambiguous.

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Finally, applicants have pointed to an unpublished decision, *ex parte Heine*. Each case must be taken on its own merits, especially when it comes to unpublished Board of Appeals decisions. Moreover, the examiner in that case did not supply references to indicate the extremely wide semantic range of the term. Indeed, the rejection was largely based on "inadequate disclosure." That is not the reasoning here.

Claims 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims refer to adducts. What kind of adducts? Adducts with what? The remarks are noted, the this material was left out of claim 13.

Claim 12 is rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

Claim 12 is either written wrong (paragraph 2) or is not enabled as written (paragraph 1). If the salt has its protecting groups removed, it will give the salt of cefdinir, not cefdinir itself.

The amendment didn't really change anything. If you deprotect the salt of protected cefdinir, you will get a salt of unprotected cefdinir. It isn't even clear if applicants intend to produce cefdinir itself or its salt.

Claims 1-15 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement

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for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims, insofar as they embrace solvates are not enabled. The examples presented all failed to produce a solvate. The evidence of the specification is thus clear: These compounds do not possess the property of forming solvates; there is no evidence that such compounds even exist. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

The traverse is unpersuasive. The examiner is not requiring examples. The examiner is not relying on his personal opinion. The examiner is relying on the actual failure of the working examples as evidence that these particular compounds do not form solvates.

Applicants state that "solvates are not something that forms very rarely or at least not readily." Agreed. They form readily, or not at all. Many compounds form solvates, and many do not, and judging from the evidence in the specification, these are in the latter category.



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The remarks then state, "The solvent molecules surround the solutes and that is a solvate.". That is mistaken. When solvent molecules surround the solutes that is merely a solution. A solvate is an actual compound, which can be crystalline or amorphous.

### *Claim Objections*

Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The compounds are all salts. This claim language does not in any way limit claim 15.

Claims 1 and 15, third from last line, each have a raised number 2 which should be subscript.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

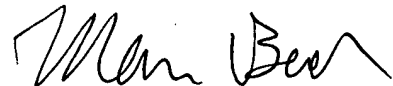
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

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In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch

Primary Examiner

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3/26/07